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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,260	03/22/2004	Jeffrey S. Kiel	455-023	1934

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EXAMINER	
VALENROD, YEVGENY	
ART UNIT	PAPER NUMBER
1621	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,260	KIEL ET AL.	
	Examiner	Art Unit	
	Yevgeny Valenrod	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETALED ACTION

Nonstatutory obviousness type double patenting rejection of claims 1-19 is withdrawn in view of the terminal disclaimer filed by the applicant on 11/25/06.

Provisional double patenting rejection of claims 1-4, 6, 8, 10-14, 19-25, 27 and 28 is maintained and is repeated below. Applicants' statement regarding addressing the rejection once patentable subject matter has been determined is noted.

Rejection of claims 1-29 under 35 USC 103 made over Chen et al in view of Gordziel is maintained. Text of the rejection is repeated below followed by Examiner' reply to Applicants' arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 6,383,471) in view of Gordziel (US 6,287,597).

Scope of prior art

Chen et al. discloses the general teaching of converting an active pharmaceutical ingredient such as gabapentin (column 6, line 33) into its tannate salt complex (column 11 line 50) by protonating the basic groups of gabapentin. Furthermore, the ionizing agent is present in an amount of at least 0.1 mole equivalent per mole of ionizable functional groups (column 11, lines 56-59)

Ascertaining the difference between the prior art and the claims at issue

Chen et al. teach converting gabapentin into gabapentin tannate. The instant invention differs from the prior art reference in that the reference fails to disclose addition of dispersing agent, excipients, pH ranges and addition of sweeteners.

Secondary reference

Gordiziel teaches a pharmaceutical composition that comprises: Pyrilamine Tannate, Pectin, Sucrose, Saccharin Sodium, Magnesium Aluminum Silicate, Water, Glycerin and Methylparaben. (column 3, Example 2). Gordiziel also teaches suspensions of the compositions and solid forms of the compositions (column 2, lines 15-22)

Obviousness

Chen et al. teach a method of producing gabapentin tannate. In order to administer the active ingredient it is common in the art to add physiologically inactive ingredients such as sweetening agents, preservatives, thickening agents, suspending agents, flavoring agents. Gordziel provides an example of a tannate salt being used in a composition that comprises all of the excipients claimed by the applicant. One of ordinary skill in the art would have been motivated to combine the method of producing gabapentin tannate as described by Chen et al with the excipients utilized by Gordzil, in order to prepare a pharmaceutical composition.

As to the pH range of 2-11 as claimed by the applicant in claim 18. A person of ordinary skill in the art would appreciate the a combination of any of the above excipients with tannic acid or gabapentin or gabapentin tannate would have a pH in the range of 2-11.

Reply to applicants' remarks

Applicant asserts that Chen et al. is not relevant prior art to the present application. The assertion is based on the fact that applicant believes that Chen et al. did not intend gabapentin to be included in the group of therapeutic agent suitable for use in the invention. This is based on the alleged definition of "ionizable hydrophobic therapeutic agents" found in column 4 lines 53-57.

Applicants' argument is noted, however it is not sufficient to rebut the fact that gabapentin is listed as a hydrophobic therapeutic agent in the specification and in the claims of Chen et al. (see claim 11, column 46, line 62).

Applicant discusses alleged unexpected results (Remarks, page 3, first full paragraph). Applicants' unexpected result is the formation of a tannate salt of gabapentin. Applicant alleges that the carboxylate group of gabapentin is expected to prevent formation of a tannate salt.

Since Chen et al. suggest formation of gabapentin tannate. Formation of the said salt is therefore not unexpected.

Claims 1-29 are unpatentable over Chen et al. absent unexpected results.

Double Patenting

Statutory

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4, 6, 8, 10-14, 19-25, 27 and 28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 of copending Application No. 10/805,806. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The claims correspond as follows: (instant claim/copending application claim) 1/1; 2/1,2; 3/3; 4/1; 6/9; 8/10; 10/8; 11/8; 12/7; 13/9; 14/9; 19/9; 20/11; 21/12; 22/13; 23/14; 24/13; 25/15; 27/16; 28/11.

Conclusion

Claims 1-32 are pending.

Claims 1-29 are rejected.

Claims 30-32 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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